Course Purpose:

The course includes methods for evaluation and improvement of drug therapy outcomes including critical appraisal of drug and clinical service literature, and quality assessment and improvement techniques with special focus on patient and medication safety.

Note: This course is approved by the Board of Pharmacy to fulfill the requirements for 2 CE Medication Safety for licensure. The Office for Student Affairs will issue a letter for every student who completes the course with grade C or higher.

The Institute of Medicine has published a series of reports that address the improvement of health care quality. Its recommendations for reinventing the health care system follow two major themes: the consequent application of evidence to health care delivery; and the full adoption of quality improvement through comprehensive use of information technology and systems that reward rather than impede quality.

This course will train pharmacy students to balance individual patient care with population-based assessment of pharmacotherapy outcomes. Evidence-based medicine requires clinicians to monitor, evaluate and implement evidence from the rapidly evolving medical literature. Students will learn how efficacy, effectiveness, safety, and efficiency data is summarized into evidence reports and clinical guidelines and learn about the limitations of this process. They will appraise original research to support clinical decision-making and to evaluate whether current practice complies with the best evidence.

Quality assessment and improvement exercises will be introduced to identify and review variation in pharmacotherapy processes and outcomes. Students will use published evidence as well as primary data to identify targets for quality improvement, to formulate strategies for identifying high-risk patients and to improve patient care, and to define process and outcome measures to evaluate patient outcomes.

Course Faculty and Office Hours

Course Coordinator:
Coordinator: Randy Hatton, BPharm, PharmD, FCCP, BCPS
Email: hatton@Prodata-Health.com  Office: TBD
Cell Phone: 352.262.0736  Home Office:

Office Hours
Office hours: by appointment, please email. Tuesdays, Thursdays, and Fridays preferred.
Place and Time of Class Sessions

Classes will meet nine times over the course of the semester; Aug. 27/28, Sep. 10/11, Sep. 17/18, Oct. 1/2, Oct. 15/16, Oct. 22/23, Nov. 5/6, Nov. 12/13, and Nov. 19/20. Please review the calendar on the course website under Resources: Calendar.

<table>
<thead>
<tr>
<th>Campus</th>
<th>Section</th>
<th>Room</th>
<th>Date and time</th>
</tr>
</thead>
<tbody>
<tr>
<td>GNV</td>
<td>5687</td>
<td>G201</td>
<td>Tues 10:40-12:35</td>
</tr>
<tr>
<td>GNV</td>
<td>5696</td>
<td>G312</td>
<td>Tues 10:40-12:35</td>
</tr>
<tr>
<td>GNV</td>
<td>7764</td>
<td>1101</td>
<td>Tues 10:40-12:35</td>
</tr>
<tr>
<td>JAX</td>
<td>7765</td>
<td>Check Sakai</td>
<td>Wed 10:00-12:00</td>
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<tr>
<td>ORL</td>
<td>7768</td>
<td>Check Sakai</td>
<td>Tues 9:00-11:00</td>
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<tr>
<td>STP</td>
<td>7770</td>
<td>Check Sakai</td>
<td>Wed 3:00-5:00</td>
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</table>

The midterm will take place on Friday Oct. 25 from 2:30-6:30PM. Classroom locations will be given sometime before then.

Your final project presentation will take place sometime between 8:00AM and 6:00PM on either Dec. 12 or Dec. 13. For planning purposes, assume that you will not be finished with the class until 6:00PM on Dec. 13.

How This Course Relates to the Learning Outcomes You Will Achieve in the PharmD Program:
This course prepares the PharmD student to accomplish the following abilities and the related Student Learning Outcomes (SLOs) upon graduation:

1. Provide Patient-centered Care - Specifically: Design, implement, monitor, evaluate, and adjust pharmacy care plans that are patient-specific; address health literacy, cultural diversity, and behavioral psychosocial issues; are evidence-based and accomplished in collaboration with other health professionals.(SLO 1.1)
2. Provide Population Health by promoting effective drug use and disease prevention/ wellness.(SLO 2.1)
3. Perform pharmacist responsibilities within the medication use system and relate to the larger health care systems to assure safe and quality patient care. (SLO 3.3)
4. Solve complex practice problems (both patient-specific and general practice) using an evidence-based approach, other aspects of good clinical science, and informatics. (SLO 8.3)

Course Objectives
The overall goal of the course is to familiarize students with methods and tools to evaluate as well as select patient-centered pharmacy services, drugs and other medical technologies. It has two components, the critical appraisal of pharmaceutical and medical literature, and the quality assessment and improvement of drug therapy and pharmaceutical care services.
Upon completion of the course students will be able to:

- Find and evaluate published medical literature for use in clinical decision-making and understand scientific reasoning and the research process in this context;
- Describe how clinical findings are summarized in evidence reports and apply them appropriately in clinical decision-making;
- Describe current evidence related to the assessment and improvement of patient safety, and the epidemiology of medication errors and adverse drug events
- Devise ways to assess the quality of pharmacotherapy for the patients seen in practice, compare differences in clinical practices and quality and their effect on patient outcomes.
- Identify opportunities for changes in practice that are feasible and effective for improving patient outcomes.
- Describe how to design, implement, and evaluate quality improvement programs.

Attitudinal objectives include the development of an appreciation for the pharmacist’s professional responsibilities and role in pharmaceutical care services, quality improvement and their impact on patient outcomes.

**Pre-Requisite Knowledge and Skills**

Successful completion of the 1PD and 2PD coursework in the PharmD program is required to take this course.

**Course Structure & Outline**

The course is split into two components following the philosophy of evidence-based medicine: critical literature appraisal and quality assessment and improvement. New content will be presented in lectures, online tutorials, and assigned readings. Content will be applied in problem-solving exercises online and in small group sessions that will meet for a 2-hour time period nine times during the course of the semester. Exercises and exams will include assessments of published evidence and proposals for quality improvement programs, and be presented in oral presentations and written reports.

1. **Critical literature appraisal will address the following issues**

   a) Introduction to evidence-based pharmacy
   b) Retrieval methods for primary medical literature, drug references and other evidence sources
   c) Methods for critical literature appraisal
   d) Study types and their relevance to study validity and application in practice
   e) Interpretation of epidemiologic measures of frequency and risk
   f) Threats to internal validity (confounding, bias, random error), hypothesis testing and scientific reasoning
   g) Generalizability and the scientific method
   h) Methods and resources for evidence summaries (meta-analysis, evidence reports, clinical guidelines)
2. Quality assessment and improvement

a) Definitions and elements of quality and examples of quality deficits in healthcare
b) Means to measure quality and current applications; selection of high-priority areas for QI
c) Aggregation of individual patient data for quality assessment: measure of process and outcomes quality
d) Methods to explore and explain variation in quality, benchmarking
e) Selection of QI strategies and plans for implementation (including screening/recruitment of high-risk patients, process measures for monitoring, design of an evaluation plan)

3. Additional content related to patient safety and drug safety

a) Review of drug safety information, methodological issues related to pharmacovigilance and post-marketing studies
b) Epidemiology of patient safety and medication errors, ascertainment and analysis of medication error data
c) Examples of medication safety initiatives

Where possible the course content will be coordinated with exercises offered by the concomitantly taught pharmacotherapy IV course as well as the statistical tests presented in the biostatistics course. This approach will allow integrating information for individual patient care decisions with the broader (population-based) perspective on how drug information is generated, how (well) it is implemented, and how drug therapy can be improved systematically.

Textbooks
The course does not use a formal textbook, but recommendations for readings will be posted. All students will be required to have an iDevice, which will be used in class.

Active Learning Requirements

• Class participation in small discussion groups, led by a facilitator.
• Completing cases, which consist of evaluating a relevant article (can be done in a group with other students) and discussing them in the small group sessions.
• Completion of online written quizzes on sample abstracts.
• Developing a QI program proposal written as a student group (final exam).
• Completing an individual critical literature appraisal (midterm exam).

Student Evaluation & Grading
This class embraces the teaching and evaluation methods described in the College of Pharmacy’s educational philosophy. The COP Educational Philosophy uses multi-faceted, active learning teaching strategies.

The course consists of weekly lectures and cases that are completed and discussed in weekly small group sessions (2 hours on a day specific to your campus). Lectures are not live. Weekly cases focus either on the retrieval or critical appraisal of selected published evidence or quality assessment and improvement exercises. Cases will be completed by students in self-study. Successful completion of the cases is evaluated through online quizzes. Students are allowed to discuss the cases, but they are responsible for presenting their own original work during the quiz and small group sessions.

Exams include a midterm paper at the end of the first 9-week period consisting of a study critique, and a quality improvement project presentation at the end of the term.

The course grade is composed of the following assignments and exams:

**Written critical literature appraisal (midterm exam).** Students will be asked to evaluate an article, which could include any type of study design and analysis that was covered in class. The exam will be completed in house and students are allowed to bring textbooks and other reference material (open book). The midterm will be in a short answer form.

**QI program proposal (final project).** Student groups will develop a quality improvement program and present their work during a formal presentation session.

**Class participation.** Students are expected to be prepared for and to participate during classes

**Cases.** Cases will be posted online weekly and evaluated using online quizzes that will be open from Mondays at 4:00PM to Tuesdays at 9:00AM (you will only have 15 minutes to complete the quiz, however). When there is a holiday on Monday (Labor Day and Veteran’s Day), quizzes will be open Sunday at 6:30PM to Tuesday at 9:00AM. When there is a law exam, quizzes will be open Monday at 11:00AM to Tuesday at 9:00AM

**Question of the day:** For the first five minutes of each small group session, students will answer a straightforward question based on the lectures, readings, and case from that week. Students will receive either full (0.5 points) or no credit. Please have a pen and paper ready for the beginning of each small group session.

**Grading Scale**

<table>
<thead>
<tr>
<th>Assignment</th>
<th>% of grade</th>
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<tbody>
<tr>
<td>Written clinical literature appraisal (midterm)</td>
<td>40%</td>
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</table>
Final quality improvement project (final project, group work of max. 5 students) | 30%
Class participation | 9%
Cases (11 of 13 online quizzes, lowest two will be dropped) | 16.5%
Questions of the day | 4.5%

**Grading system:**

Scores from each of the assignments and exams will be combined to calculate a total score. Final grades will be assigned according to the following scheme:

- A: 93.0 - 100
- A-: 90.0 – 92.9
- B+: 87.0 – 89.9
- B: 83.0 – 86.9
- B-: 80.0 – 82.9
- C+: 77.0 – 79.9
- C: 73.0 – 76.9
- C-: 70.0 – 72.9
- D+: 67.0 – 69.9
- D: 63.0 – 66.9
- D-: 60.0 – 62.9
- E: <60

**Class Attendance Policy**

Unexcused absences from the group discussions carry a 5-point (1/2 letter grade) penalty taken off the final grade. Absences due to illness and other emergencies must be conveyed by e-mail to your lab facilitator, Dr. Hatton (hatton@Prodata-Health.com) and copied to TA Chao Chen (charl.coverc@ufl.edu) before the group discussion begins. Email is preferred but a telephone call will be accepted if you cannot email. Messages from friends will not be accepted.

**Quiz/Exam Policy**

Students can request re-evaluation of complete written assignments (e.g., the midterm exam) within 3 weeks after the grade was received. In requesting a re-evaluation, students agree to accept any adjustment to their grade (negative or positive) that may be proposed by the re-grading.
Make-up Quiz/Exam Policy

Make-up exams for the midterm and final project presentation will be handled by the course coordinator on a case-by-case basis.

Policy on Old Quizzes and Assignments

Samples of previous years’ midterms will be provided to students in an appropriate time period before the midterm.

Assignment Deadlines

Assignments (online quizzes and the QI project) will be posted with explicit due dates. Students are responsible for complying with these deadlines. Late assignments will not be graded (0 points). Delays due to unforeseen and/or distressing events will be treated on a case-by-case basis by the course coordinator.

For online quizzes, please prepare for the event that you may be disconnected from the Sakai System for some reason by copying the quiz questions into a word document. Emails with the answers that are received within the time limit for quiz completion will be accepted as equivalent to online completion of the quiz; send to TA Yanmin (Zoe) Zhu (zoe3695@ufl.edu).

General College of Pharmacy Course Policies

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

Complaints

Should you have any complaints with your experience in this course please contact your course coordinator. If unresolved, contact the COP Senior Associate Dean-Professional Affairs. For unresolved issues, see:
http://www.distancelearning.ufl.edu/student-complaints to submit a complaint.

Other Course Information

iDevices:

iDevices will be used in class to actively engage students through general polling during discussions to better understand how well you are understanding the material. Registration of iDevices is not necessary. Please verify your license is still valid; you can do this by running ResponseWare on your iDevice. The expiration date is displayed under your deviceID. Prior to class, you will need to logon to the HSC wireless network with your password. To participate in class, your instructor will provide you a SessionID to answer the questions on your iDevice. Please consult the “Connecting to a Turning Point Session” tutorial located in the course website for additional details. You are responsible for bringing your iDevice to class and maintaining it in operating order.
Appendix A: Directions for Contacting Faculty & Course Faculty List

Directions for Contacting Course Faculty

Sakai will be used for most communications between the faculty and students. Check for new announcements at least once a day for any course updates. Email will also be used once in a while for mass communication to the class, so please check your email at least once a day as well. All emails sent out to the entire class will also be posted as an announcement on Sakai.

General questions about course content (e.g., assignments or lectures) or policies should be posted to the discussion board. We expect students to help each other track down answers as best as possible. Read through all the other posts in the discussion board first before posting to make sure your question has not been addressed/answered already. Please include clear subjects for your post topics to make it clear to all what your post pertains to.

Emotions can easily be misinterpreted on a discussion board/emails so make sure your message is clear before sending it since there are no physical gestures or voice inflections that accompany posts/emails. Any posts/emails deemed inappropriate by the faculty will be dealt with on a case by case basis with either the faculty directly or they will be sent on to the Associate Dean for Professional Affairs.

For personal issues/questions please email your facilitator directly and copy Dr. Hatton (hatton@Prodata-Health.com). If you have any issues with the course site please email TA Yanmin (Zoe) Zhu (zoe3695@ufl.edu). Be sure to include in your subject line the course listing and then a quick subject (i.e. PHA5226 – Your Name - Cat got sick this morning). This will allow coordinators to easily identify emails related to the course amongst the plethora of junk and other emails that are received each day. Emails not properly addressed may get lost in the shuffle and unintentionally deleted or ignored so be sure to follow the guidelines exactly.

Course Coordinator

Randy C. Hatton, BPharm, PharmD, FCCP, BCPS  hatton@Prodata-Health.com

Facilitators and TA’s

Bernadette Belgado, PharmD JAX co-facilitator bernadette.belgado@jax.ufl.edu
Chao Chen, BPharm GNV TA charl.coverc@ufl.edu
Chintan Dave, PharmD GNV TA cdave@ufl.edu
Paul L. Doering, RPh, MS GNV facilitator doerip@shands.ufl.edu
Juan Hincapie Castillo, PharmD GNV TA j.hincapie@ufl.edu
Wei Liu, GNV facilitator wei.liu@ufl.edu
Susan J. Markowsky, PharmD STP facilitator smarkowsky@cop.ufl.edu
Russell McKelvey, PharmD JAX co-facilitator russell.mckelvey@jax.ufl.edu
Donna Rivera, PharmD GNV TA drsimpson@ufl.edu
Lisa Vandervoort, PharmD ORL facilitator lvandervoort@cop.ufl.edu
Yanmin (Zoe) Zhu, GNV TA zoe3695@ufl.edu
### Appendix B. Schedule of Course Activities/Topics

<table>
<thead>
<tr>
<th>Week</th>
<th>Instructor</th>
<th>Learning Activities/Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>All</td>
<td>Searching the literature, case reports, drug safety, studies without a control group</td>
</tr>
<tr>
<td>2</td>
<td>All</td>
<td>RCT’s</td>
</tr>
<tr>
<td>3</td>
<td>All</td>
<td>RCT’s</td>
</tr>
<tr>
<td>4</td>
<td>All</td>
<td>Non-inferiority studies</td>
</tr>
<tr>
<td>5</td>
<td>All</td>
<td>Observational studies</td>
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<tr>
<td>6</td>
<td>All</td>
<td>Observational studies</td>
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<tr>
<td>7</td>
<td>All</td>
<td>Observational studies</td>
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<tr>
<td>8</td>
<td>All</td>
<td>Observational studies</td>
</tr>
<tr>
<td>9</td>
<td>All</td>
<td>Meta-analyses</td>
</tr>
<tr>
<td>10</td>
<td>All</td>
<td>Intro to QI (Quality improvement studies) / midterm</td>
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<tr>
<td>11</td>
<td>All</td>
<td>Root cause analysis</td>
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<tr>
<td>12</td>
<td>All</td>
<td>QI studies</td>
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<tr>
<td>13</td>
<td>All</td>
<td>QI studies</td>
</tr>
<tr>
<td>14</td>
<td>All</td>
<td>Quasi-experimental studies</td>
</tr>
<tr>
<td>15</td>
<td>All</td>
<td>Determining impact of QI interventions</td>
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